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TITLE: New chimeric human papillomavirus (HPV) L1 proteins, useful for eliciting antibody responses or cellular responses against papillomavirus, and as therapeutic, prophylactic or diagnostic reagents for papillomavirus infection

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PRIORITY-DATA: 2000US-212839P (June 21, 2000)

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## PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
<input type="checkbox"/> EP 1292328 A1	March 19, 2003	E	000	A61K039/12
<input type="checkbox"/> WO 200197840 A1	December 27, 2001	E	049	A61K039/12
<input type="checkbox"/> AU 200175458 A	January 2, 2002		000	A61K039/12

INT-CL (IPC): A61 K 39/00; A61 K 39/12; C12 N 7/00; C12 P 21/06

ABSTRACTED-PUB-NO: WO 200197840A

## BASIC-ABSTRACT:

NOVELTY - A chimeric human papillomavirus (HPV) L1 protein, which is capable of eliciting antibody responses or cellular responses that are generally comparable to those induced by two or more individual HPV types, is new.

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for the following:

- (1) a virus-like particle (VLP) comprising the chimeric HPV L1 protein;
- (2) a vaccine composition comprising the chimeric HPV L1 protein;
- (3) a therapeutic composition comprising the chimeric HPV L1 protein;
- (4) a gene encoding the chimeric HPV L1 protein;
- (5) a baculovirus vector comprising the gene;
- (6) inducing a high titer neutralizing antibody response or cell-mediated immune response against at least two HPV types by administering a single type of chimeric HPV L1 protein, or a VLP comprising a single type or at least two types of chimeric HPV L1 proteins;
- (7) antisera generated by the method of (6);

(8) vaccinating a subject against at least two types of HPV by administering a vaccine composition, comprising at least one correctly folded chimeric HPV L1 protein, where the chimeric HPV L1 protein comprises neutralizing epitopes for at least two HPV types;

(9) treating a papillomavirus infection:

(a) characterized by more than one HPV type by administering a therapeutic composition having HPV VLPs displaying at least one chimeric L1 proteins;

(b) caused by a first HPV type, concurrently with prophylactic treatment of at least one other type of HPV infection, by administering a therapeutic composition with HPV VLPs displaying at least one chimeric L1 protein;

(10) making a multi-HPV type vaccine or therapeutic composition; and

(11) diagnosing prior or current papillomavirus infection.

#### ACTIVITY - Virucide.

Groups of Swiss mice (5 mice/group) were immunized with three of the four different chimeric VLPs as well as HPV-18 and HPV-45 VLPs adsorbed to aluminum hydroxide. Pooled serum samples, collected after the secondary immunization, were screened by enzyme linked immunosorbent assay (ELISA) for reactivity with HPV-18 and HPV-45 VLPs. Both the XN and NB chimerics elicited antisera that strongly reacted with both HPV-18 and HPV-45 VLPs. In contrast, antisera against the BH chimeric in which C' terminal end (amino acids 449-506) of HPV-18 L1 were replaced with the analogous region of HPV-45 L1, reacted poorly with HPV-45 VLPs.

#### MECHANISM OF ACTION - Immunotherapy.

USE - The chimeric HPV L1 protein is useful for eliciting antibody responses or cellular responses against papillomavirus infections. The chimeric HPV L1 protein are also useful as therapeutic and prophylactic reagents, as well as reagents for diagnosing papillomavirus infection. It may also be used as effective prophylactic reagents against the disease states associated with prolonged infections with the HPV types. Chimeric VLPs may be useful in the diagnosing prior or current infection with the HPV types or as an aid in the determination of the level of protective (neutralizing) antibody present in a body fluid sample.

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EQUIVALENT-ABSTRACTS:

CHOSEN-DRAWING: Dwg.0/7